IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, Plaintiff, v. AEGERION PHARMACEUTICALS, INC., a corporation and DR. CHARLES M. GERRITS, an individual, Defendants.	Civil Action No. _____

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a complaint for permanent injunctive relief against Aegerion Pharmaceuticals, Inc. ("Aegerion"), a corporation, and Dr. Charles M. Gerrits (who was hired by Aegerion and assumed his position as Senior Vice President for Global Market Access, Patient Advocacy, and REMS in January 2017, after all the investigations described in the Complaint were completed), an individual (collectively, "Defendants"), and Defendants, having consented to entry of this Decree without contest, without admitting or denying the allegations in the Complaint, and disclaiming any liability in connection therewith except for Aegerion as to the admissions Aegerion makes in the plea agreement in *United States v. Aegerion, Inc.*, Criminal Action No. (to be assigned) (D. Mass.), and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and personal jurisdiction over all parties to this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 332(a).

2. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c).

3. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. (the "Act"). This Decree is in accordance with the Act and the Court's inherent equitable authority.

4. The government alleges that Aegerion violated the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce articles of drug that were misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling bore inadequate directions for use, and 21 U.S.C. § 352(y) in that Defendants failed to comply with a Risk Evaluation and Mitigation Strategy ("REMS") pursuant to 21 § U.S.C. 355(p).

5. The government also alleges that Aegerion violated the Act, 21 U.S.C. § 331(k), by doing acts that resulted in the misbranding of articles of drug, within the meaning of 21 U.S.C. § 352(f)(1) and 21 U.S.C. § 352(y), while such drugs were held for sale after the shipment of one or more of their components in interstate commerce.

DEFINITIONS

6. For purposes of this Decree, the following definitions shall apply:

   A. "Associated Persons" means each and all of Aegerion's directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them who are engaged in the operation of the Juxtapid REMS Program (including individuals, directors,

partnerships, corporations, subsidiaries, and affiliates) and who receive actual notice of this Decree by personal service or otherwise.

B. "Days" refers to calendar days, including all Saturdays, Sundays, and federal holidays.

C. "Detailing," in the context of this Decree, means interaction by, or at the direction of, a Covered Person with a healthcare provider, in person, by telephone, email, or other electronic media, or by direct mail, for the purpose of promoting Juxtapid.

D. "Drug(s)" shall have the meaning given the term in 21 U.S.C. § 321(g)(1).

E. "Covered Persons" includes:

i. all Aegerion employees engaged in or directly responsible for: (a) the selling, detailing, marketing, advertising, promoting, or branding of Juxtapid; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Juxtapid, including those functions relating to Aegerion's review and approval processes for promotional materials and any applicable review committee(s);

ii. all Aegerion employees engaged in activities related to compliance with or training on any REMS Program requirements for Juxtapid; and

iii. all contractors, agents and other persons engaged in (a) the selling, detailing, marketing, advertising, promoting, or branding of Juxtapid; (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Juxtapid, including those functions relating to Aegerion's review and

approval processes for promotional materials and any applicable review committee(s); or (c) activities related to compliance with or training on any REMS Program requirements for Juxtapid.

F. "Juxtapid" is the trade name of the pharmaceutical drug, lomitapide mesylate, approved by the FDA as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

G. "Juxtapid REMS Program" means all elements of the Risk Evaluation and Mitigation Strategy applicable to Juxtapid as of the date this Decree is entered, including any modifications of the REMS, or any changes to the Juxtapid REMS accepted by FDA during the term of this Decree.

INJUNCTION PROVISIONS

7. Defendants and each and all of their Associated Persons are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done, at any location, any act that:

A. violates 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, any article of drug that is misbranded within the meaning of 21 U.S.C. §§ 352(f)(1) and 352(y); and,

B. violates 21 U.S.C. § 331(k) by causing any drug to become misbranded within the meaning of 21 U.S.C. §§ 352(f)(1) and 352(y), while such drug is held for sale after shipment in interstate commerce.

8. Upon entry of this Decree, Defendants shall, consistent with the Juxtapid REMS Program:

A. With respect to healthcare providers:

i. provide mechanisms for healthcare providers to complete the certification process for the Juxtapid REMS Program by email and fax;

ii. notify healthcare providers when they are certified by the Juxtapid REMS Program;

iii. maintain a validated, secure database of healthcare providers who are certified to prescribe Juxtapid in the Juxtapid REMS Program;

iv. require that healthcare providers who prescribe Juxtapid be certified in compliance with the Juxtapid REMS Program and complete a Juxtapid REMS Program Prescription Authorization Form for each new Juxtapid prescription;

v. investigate all instances of healthcare provider potential noncompliance with the Juxtapid REMS Program requirements;

vi. de-certify any healthcare provider who has demonstrated a pattern of noncompliant prescribing, defined as any healthcare provider who Aegerion determines, after completing its investigation, has not complied with the Juxtapid REMS Program requirements on two or more occasions;

vii. provide the Juxtapid REMS Program Fact Sheet, Juxtapid REMS Program Prescriber Training Module, Juxtapid REMS Program Patient Guide, Juxtapid REMS Program Patient-Prescriber Acknowledgement Form, Juxtapid REMS Program Prescription Authorization Form and the

Juxtapid Prescribing Information to healthcare providers who (1) attempt to prescribe Juxtapid and are not yet certified, or (2) inquire about how to become certified; and

viii. ensure that the *REMS Letter for Healthcare Providers* that was sent on February 22, 2017 and made available on the Juxtapid REMS Program Website (www.juxtapidREMSprogram.com) be available upon request from the Juxtapid REMS Program by phone at 1-855- JUXTAPID (1-855-898-2743).

B. With respect to pharmacies:

i. require pharmacies that seek to dispense Juxtapid to designate an authorized representative;

ii. require such pharmacies' authorized representatives to complete and submit to Aegerion the Juxtapid REMS Program Pharmacy Enrollment Form;

iii. notify pharmacies when they are certified by the Juxtapid REMS Program;

iv. ensure that certified pharmacies are provided access to a database of certified prescribers and patients who have a completed Juxtapid REMS Program Patient-Prescriber Acknowledgement Form;

v. verify every twelve (12) months that the authorized representative's name and contact information corresponds to that of the current designated authorized representative for the certified pharmacy;

vi. require certified pharmacies to recertify in the Juxtapid REMS Program if a pharmacy designates a new authorized representative;

vii. require certified pharmacies to maintain, and make available to Aegerion or a third party acting on behalf of Aegerion, documentation, including prescription data and training and verification records, to demonstrate that all processes and procedures are in place and are being followed for the Juxtapid REMS Program; and,

viii. require certified pharmacies to comply with audits by Aegerion, FDA, or a third party acting on behalf of Aegerion or FDA to ensure that all processes and procedures are in place and are being followed for the Juxtapid REMS Program.

C. With respect to the evidence of safe-use conditions for Juxtapid:

i. require that patients or their caregivers sign a Juxtapid REMS Program Patient-Prescriber Acknowledgement Form indicating that the patient has: (a) received and read the Juxtapid REMS Program Patient Guide; and (b) received counseling from his or her prescriber regarding the risk of hepatotoxicity, the need for periodic liver function monitoring, and appropriate patient selection for Juxtapid;

ii. provide mechanisms for certified prescribers to be able to submit completed Juxtapid REMS Program Patient-Prescriber Acknowledgement Forms by email and fax;

iii. require that, before dispensing Juxtapid, pharmacies have: (a) reviewed the Prescribing Information and the Juxtapid REMS Program Fact Sheet; (b) completed the Juxtapid REMS Program Pharmacy Training Module and successfully completed the Knowledge Assessment; and (c) trained all

relevant staff on appropriate procedures for dispensing Juxtapid in accordance with the Juxtapid REMS Program Pharmacy Training Module;

iv. require that certified pharmacies dispense Juxtapid to patients only if they can verify that, for each Juxtapid prescription there is: (a) a completed Juxtapid REMS Program Patient-Prescriber Acknowledgement Form; and (b) a prescription from a certified prescriber; and

v. require that certified pharmacies only fill new Juxtapid prescriptions if they can verify that there is a completed Juxtapid REMS Program Prescription Authorization Forms for each new Juxtapid prescription.

D. Submit to FDA, at least ninety (90) days before administering, any survey methodology and protocols to which Defendants have made substantive changes (which methodology and protocols shall include at least: the target sample size; precision estimates associated with that sample size; a list of specific criteria that will be used to select participants in the survey; a description of how and when the surveys will be administered; an explanation of the design features and controls that will be included to minimize bias and compensate for any limitations in the methodology; and a copy of the survey questionnaire), for the following surveys:

i. a "Knowledge, Attitudes, and Behavior" ("KAB") survey of a random sample of certified prescribers to determine, for Juxtapid, prescribers' awareness and understanding of: (a) the indication for use; (b) the risk of hepatotoxicity, including appropriate evaluation, monitoring and counseling to minimize this risk as described in the Prescribing

Information, the Fact Sheet, and the Prescriber Training Module; (c) the Juxtapid REMS Program materials; and, (d) the Juxtapid REMS Program requirements; and

ii. a Patient Knowledge survey to evaluate patient understanding of the Juxtapid REMS goals concerning the risk of hepatotoxicity and the need for baseline and periodic monitoring.

E. Receive written approval from FDA for the KAB and Patient Knowledge protocols, including any amended protocols, before administering either survey.

9. Nothing in this Decree shall affect the date by which prescribers and pharmacies must be recertified in accordance with the Juxtapid REMS Program approved by FDA on January 3, 2017, and any changes thereto approved by FDA or otherwise accepted by FDA.

10. Nothing in this Decree shall alter Defendants' requirement under the Juxtapid REMS Program to submit written assessments to FDA or FDA's ability to change the timetable for such assessments under the Juxtapid REMS Program, including by reducing the frequency of or eliminating the requirement to submit such assessments. The requirements of this Decree are in addition to, and not instead of, the Juxtapid REMS Program reporting requirements.

11. Within ninety (90) days of entry of this Decree, Defendants shall retain an independent person or persons (the "Auditor") at Aegerion's expense to review and monitor Defendants' activities related to the Juxtapid REMS Program not less than once every twelve (12) months for a period of five (5) years. The Auditor shall be qualified by education, training, and experience to conduct such audits, and shall be without personal or financial ties (other than a consulting agreement with Defendants) to Defendants'

officers or employees or their immediate families. Defendants shall notify FDA in writing of the identity and qualifications of the Auditor as soon as they retain such Auditor. The Auditor shall evaluate the Defendants' REMS Assessment Reports ("REMS Assessments") for any non-compliance with the Juxtapid REMS Program. Specifically, the Auditor shall, consistent with the Juxtapid REMS Program:

A. Evaluate Defendants' implementation of the KAB and Patient Knowledge Surveys and whether Defendants adhered to the protocols and methodologies approved by FDA in Paragraph 8(E).

B. Evaluate Defendants' communications with certified prescribers and certified pharmacies. The Auditor shall determine whether each REMS Assessment includes, at a minimum:

   i. the date of mailing and number of recipients of the REMS Letter for Healthcare Providers and REMS Letter for Pharmacists;

   ii. the number of mailings returned;

   iii. a representative copy of all documents included in each mailing;

   iv. a summary of issues and complaints received by the Juxtapid REMS Program Call Center and a summary how these issues and complaints were resolved; and

   v. a summary of the reasons (and numbers per reason) for calls into the Juxtapid REMS Program Call Center.

C. Evaluate Defendants' compliance with the prescriber certification requirements. The Auditor shall determine whether each REMS Assessment includes, at a minimum:

i. the number of healthcare prescribers certified or re-certified in the Juxtapid REMS Program during the reporting period and cumulatively (stratified by prescriber degree, practice setting, geographic location and specialty);

ii. the volume of prescriptions for each prescriber and each specialty, including a full breakdown of prescribing specialties contained in the "other" category;

iii. the specialties of any "high volume" prescribers, i.e., those who write more than four (4) prescriptions in an assessment period and cumulatively, including a full breakdown of prescribing specialties contained in the "other" category;

iv. a summary of the method prescribers used to enroll during the reporting period and cumulatively; and

v. the number of healthcare providers that had their certification revoked during the reporting period and cumulatively and the reason for the revocation.

D. Evaluate Defendants' compliance with the wholesaler/distributor authorization requirements. The Auditor shall determine whether each REMS Assessment includes, at a minimum:

i. the number of wholesalers/distributors that were authorized in the REMS program, during the reporting period and cumulatively;

ii. the number of wholesalers/distributors that had their authorization revoked during the reporting period and cumulatively and the reason for the revocation;

iii. the number of Juxtapid orders shipped to pharmacies during the reporting period and cumulatively, including number of bottles, bottle size, and dosage strength; and

iv. the number of Juxtapid orders shipped to non-certified pharmacies.

E. Evaluate Defendants' compliance with the pharmacy enrollment and metrics requirements. The Auditor shall determine whether each REMS Assessment includes, at a minimum:

i. the number of pharmacies that were certified or re-certified in the Juxtapid REMS Program during the reporting period and cumulatively;

ii. the number of pharmacies that had their certification revoked during the reporting period and cumulatively and the reason for the revocation;

iii. the number of new Juxtapid prescriptions received;

iv. the total number of prescriptions dispensed for Juxtapid, including quantity of capsules (mean, minimum, and maximum) and dosage strength during the reporting period and cumulatively;

v. the total number of Juxtapid prescriptions that were: (a) received from certified and non-certified healthcare providers; (b) dispensed without a signed attestation on the Juxtapid REMS Program Prescription Authorization Form; or (c) dispensed without a completed Juxtapid REMS Program Patient-Prescriber Acknowledgement Form;

vi. the number and details concerning any prescribers that submitted an altered Juxtapid REMS Program Prescription Authorization Form, and whether pharmacies dispensed Juxtapid in response to such forms;

vii. the number and demographics (e.g., including gender, age, geographic location) of unique patients who received Juxtapid during the reporting period and cumulatively, calculated by reconciling orders dispensed to unique patients;

viii. duration of therapy for patients (mean, median, and range);

ix. the number of prescriptions pending or canceled, and an explanation for their status, including the specific criterion used to classify a prescription as canceled;

x. the number, length, and reasons for shipment delays to patients and whether or not these reasons were related to the REMS, and any additional information from insurance payers as to the reason for delay/non-payment; and

xi. the percentage of fill delays that involve new prescriptions versus refills.

F. Evaluate whether the Juxtapid REMS Program and Defendants' implementation thereof is meeting the goal to mitigate the risk of hepatotoxicity associated with Juxtapid, and whether Defendants have:

i. included a detailed description of root cause of any noncompliance with the REMS Program, and any corrective and/or preventive actions taken to address the noncompliance;

ii. provided an analysis of the post-marketing cases of specific hepatic adverse events reported in association with Juxtapid during the reporting period and cumulatively, and the outcome of such analysis;

iii. specified measures that will be taken to increase awareness if the KAB survey indicates inadequate prescriber awareness of the risks associated with Juxtapid; and

iv. assessed the extent to which each approved strategy, including each element of each strategy, is meeting the goal or whether one or more such strategies or such elements should be modified.

G. Prepare a written audit report (the "Audit Report") at the conclusion of each Audit, synthesizing the Auditor's observations, analyzing whether Defendants' operations are in compliance with the Juxtapid REMS Program and this Decree with respect to the Juxtapid REMS Program, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). Each Audit Report shall:

i. list all records and information reviewed by the Auditor in connection with the report, including, but not limited to, call notes, emails, message recall studies, and prescription data, and whether the Auditor requires additional information or materials to evaluate compliance;

ii. assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations;

iii. include the survey results and summaries and analyses for all of the completed KAB and Patient Knowledge surveys, if not included in Defendants' REMS Assessment;

iv. contain a written assessment of the Defendants' compliance with the requirements of the Act, its regulations, and this Decree with respect to its operation of the Juxtapid REMS program, including any adverse observations that indicate inconsistency with the Juxtapid REMS Program and goals; and,

v. be completed and delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than sixty (60) days after Defendants submit each REMS Assessment to FDA.

12. Defendants shall maintain complete Audit Reports and all of their underlying data in readily accessible files at their facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request. Additionally, if an Audit Report contains any Audit Report Observations, Defendants shall, within forty-five (45) days after receipt of the Audit Report, take action to correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that any action it plans to take to correct any Audit Report Observation will take longer than forty-five (45) days, or any shorter period required by FDA, Defendants shall, within fifteen (15) days after receipt of the Audit Report, propose a schedule for completing such actions ("Action Schedule") and provide justification for the additional time. That Action Schedule must be reviewed and approved by FDA in writing. Defendants shall complete all corrections according to the approved Action

Schedule and notify the Auditor when such actions are complete. Within thirty (30) days after being notified that Defendants have taken actions to correct the Audit Report Observations, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observation(s). Within fifteen (15) days of completing the review, the Auditor shall complete and deliver a written report contemporaneously to Defendants and FDA by courier service or overnight delivery service addressing whether each of the Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected; explaining the Auditor's basis for such a determination; and identifying the actions required by Defendants to correct each of the Audit Report Observations.

13. In the event Defendants replace the Auditor required by this Decree, Defendants shall notify FDA in writing of this change within thirty (30) days after such replacement. In satisfying the requirements of this Decree, any Auditor may review the previous Auditor's work, and refer to such work to satisfy the requirements of the Decree; however, when such work is referenced by the new Auditor, he or she shall identify the specific prior work referenced.

14. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, a report submitted by Defendants, the Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, the Act, or its implementing regulations with respect to the operation of the Juxtapid REMS Program, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations with respect to the operation of the Juxtapid REMS Program, FDA may, as and when it deems necessary, notify Defendants

in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease selling, detailing, and/or distributing Juxtapid;

B. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

C. Submit additional reports or information to FDA as requested;

D. Issue a safety alert; and/or

E. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations with respect to the Juxtapid REMS Program, including instituting or re-implementing any of the requirements set forth in this Decree.

The provisions of this Paragraph shall be apart from, and in addition to, all other remedies available to FDA.

15. The following process and procedures shall apply in the event that FDA issues an order under Paragraph 14:

A. Upon receipt of any order issued by FDA pursuant to Paragraph 14, Defendants shall, within ten (10) business days after receiving such order, notify FDA in writing either that: (i) Defendants are undertaking or have undertaken corrective action(s), in which event Defendants shall describe the specific action(s) taken or proposed to be taken and the proposed schedule for completing the action(s); or (ii) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis

for their disagreement; in doing so, Defendants may also propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's notice of affirmation or modification, immediately implement the order (as modified, if applicable), and, if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, as modified if applicable, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. Any review of FDA's order under this Paragraph shall be made in accordance with the terms set forth in Paragraph 32.

D. The procedures set forth in Paragraphs 15(A)-15(C) shall not apply to any order issued under Paragraph 14 if such order states that it is based on FDA's judgment that the matter raises significant public health concerns, and FDA's judgment and basis for such decision are stated in the order. In such case, Defendants shall immediately and fully comply with the terms of that order. If they so choose, Defendants may bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. Any review of

FDA's order under this Paragraph shall be made in accordance with the terms set forth in Paragraph 32.

E. Any cessation of operations or other action described in Paragraphs 14 or 15 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations with respect to the operation of the Juxtapid REMS Program, and that Defendants may resume operations. Defendants may at any time submit a request to FDA in writing to discontinue any cessation of operations or other action described in Paragraph 14. After receiving Defendants' written request to resume operations, FDA will determine whether it needs to inspect any of Defendants' facilities to determine Defendants' compliance with this Decree, the Act, and its implementing regulations with respect to the operation of the Juxtapid REMS Program. If FDA determines that an inspection is necessary, it shall conduct the inspection and determine whether Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations with respect to the operation of the Juxtapid REMS Program, and, if so, FDA will issue to Defendants a written notification permitting resumption of operations. Irrespective of FDA's decision to conduct an inspection, FDA will decide within sixty (60) days after receipt of the Defendants' written request whether Defendants appear to be in compliance and, if so, issue to Defendants a written notification permitting resumption of actions described in Paragraph 14. The cost of FDA's inspections, sampling, testing, travel time, and subsistence expenses to

implement the remedies set forth in Paragraphs 14 and 15 shall be borne by Defendants at the rates specified in Paragraph 27.

16. Within thirty (30) days after entry of this Decree, Defendants shall post a letter in a prominent place on the main page of its company website and for a period of three years thereafter. This letter shall be dated and shall be signed by Aegerion's Board Chair and shall contain the language set forth below:

> As you may be aware, Aegerion Pharmaceuticals, Inc. (Aegerion) recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with Aegerion's promotion and sales of its product Juxtapid. This letter provides you with additional information about the global settlement, explains Aegerion's commitments going forward, and provides you with access to information about those commitments.
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> In general terms, the Government alleges that Aegerion engaged in several types of unlawful and improper conduct. More specifically, the Government alleges that Aegerion unlawfully distributed Juxtapid for intended uses not approved by FDA and failed to comply with a Risk Evaluation and Mitigation Strategy required by the FDA for Juxtapid. The Government also alleges that certain Aegerion employees made false and misleading statements about Juxtapid, that the company violated certain patient privacy requirements, and that Aegerion made payments to an independent charity for patient co-payment assistance that violated the Anti-kickback Statute.
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> To address these issues, Aegerion pleaded guilty to violating the Federal Food, Drug, and Cosmetic Act and agreed to pay approximately $7 million in criminal fines and forfeiture. Aegerion also entered into a five-year Deferred Prosecution Agreement to resolve claims that it violated the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Separately, Aegerion agreed to enter into a civil Consent Decree of Permanent Injunction to be monitored by the U.S. Food and Drug Administration (FDA).
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> In addition, the federal government and several individual states alleged that Aegerion's conduct violated the federal False Claims Act and equivalent state statutes. To resolve those allegations, Aegerion entered into a separate civil False Claims Act settlement whereby Aegerion agreed to reimburse federal and state health care programs approximately $29 million.
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> Finally, the Securities and Exchange Commission alleged that Aegerion's conduct violated federal security statutes. To resolve those allegations, Aegerion entered into a separate civil securities settlement whereby Aegerion agreed to pay

> approximately $4 million. Copies of and more information about these settlements may be found at the following website:
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> https://www.justice.gov/civil/current-and-recent-cases#_Pharm2
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> As part of the global settlement, Aegerion also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at http://oig.hhs.gov/fraud/cia/index.html. Under this agreement, Aegerion agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by Aegerion's representatives to Aegerion's Compliance organization or the FDA using the information set out below. Please call Aegerion at 1-855-463-8974 or visit us at http://novelion.com/about-novelion/aegerion-pharmaceuticals/aegerion-government-settlement if you have questions about the settlement referenced above. Please call Aegerion at 1-855-233-8089 or visit us at https://novelioncompliance.tnwreports.com to report any instances in which you believe that an Aegerion representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by an Aegerion Representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200.You should direct medical questions or concerns about Aegerion products to 1-855-303-2347 or http://www.novelion.com/physician-resources/global-medical-information.

Within thirty five (35) days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of their compliance with this Paragraph.

17. Within thirty (30) days after entry of this Decree, Defendants shall communicate to all Covered Persons that Defendants have entered into this Decree and describe the terms and obligations of this Decree. Within thirty-five (35) days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of their compliance with this Paragraph and a copy of the communication(s) sent pursuant to this Paragraph.

18. Within fifteen (15) days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service, electronic mail, or certified mail (return receipt requested) to

each and all Covered Persons and Associated Persons. Within twenty (20) days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this Paragraph, and identifying the names, street or electronic mail addresses (as applicable), and positions of all persons who have received a copy of this Decree in accordance with this Paragraph.

19. In the event that any of the Defendants becomes associated with additional Associated Persons at any time after entry of this Decree, Defendants shall, within fifteen (15) days of the commencement of such association, provide a copy of this Decree, by personal service, electronic mail, or certified mail (restricted delivery, return receipt requested), to such Associated Persons. Defendants shall, every twelve (12) months, provide FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this Paragraph, identifying the names, street or electronic mail addresses (as applicable), and positions of all Associated Persons who received a copy of this Decree pursuant to this Paragraph. Within ten (10) days of receiving a request from FDA for any information or documentation FDA deems necessary to evaluate compliance with this Paragraph, Defendants shall provide such information or documentation to FDA.

20. Aegerion shall notify FDA, in writing, at the address specified in Paragraph 29, at least ten (10) days before any change in ownership, character, or name of their business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchises, affiliates, or "doing business as" entities that may affect the operations, assets, rights, or liabilities of Aegerion in the

United States, or any other change in the organizational structure of Aegerion or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Aegerion shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) days before any sale or assignment. Aegerion shall furnish FDA with an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of their compliance with this Paragraph no later than ten (10) days prior to such assignment or change in ownership.

21. Should Aegerion intend to permanently transfer all rights to Juxtapid, including the responsibilities related to its marketing, compliance with the FDCA and its implementing regulations, and the Juxtapid REMS, it must notify FDA as required by Paragraph 20, and provide FDA, within ten (10) days, with any additional information about the transaction that the agency may request. No sooner than sixty (60) days after providing FDA with any additional information requested by the agency under this Paragraph, or if no such information is requested within sixty (60) days of Aegerion providing notice under Paragraph 20, Aegerion may petition the Court to substitute the entity obtaining the rights to Juxtapid as the corporate Defendant under this Consent Decree ("Substitute Corporate Defendant"). Aegerion shall remain bound as the Corporate Defendant under this Decree unless and until the Substitute Corporate Defendant agrees in writing to be bound by this Consent Decree and is so ordered by the Court.

22. If Defendant Gerrits's responsibilities are materially reduced or altered, or his position is eliminated, Aegerion shall petition the Court to substitute for him an individual Defendant that is either his successor or the individual or individuals vested with the

responsibility for the Juxtapid REMS program and regulatory compliance with the Act, its regulations, and this Decree. If removing an individual Defendant would result in no individual Defendant being subject to this Decree, Aegerion shall designate an individual or individuals of similar position and responsibility to be substituted as Defendant(s) ("Substitute Individual Defendant(s)"), and provide FDA with the name(s), position description(s), and organizational chart(s) demonstrating the position and responsibilities for the proposed Substitute Individual Defendant(s). Aegerion shall petition the Court to substitute the Substitute Individual Defendant(s) for Defendant Gerrits's and the United States will not oppose such a motion so long as FDA has sufficient evidence or information regarding the position and responsibilities of the proposed Substitute Individual Defendant(s).

23. FDA shall be permitted, without prior notice and when FDA deems necessary, to make inspections of the Defendants' place(s) of business during reasonable times and within reasonable limits and in a reasonable manner, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and FDA regulations with respect to the Juxtapid REMS Program. During inspections, FDA shall be permitted to have ready access to buildings, equipment, products, labeling, and other materials therein; take photographs and make video recordings; take samples of Defendants' products, containers, packaging material, labeling, and other materials; and examine and copy all records relating to the importing, receiving, manufacturing, preparing, processing, packing, labeling, holding, and/or distributing of any and all drugs and their respective components. FDA will provide Defendants with a receipt for any samples taken pursuant to 21 U.S.C. § 374 and with

copies of any photographs and video recordings made, upon a written request by Defendants and at Aegerion's expense. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

24. Defendants' obligations under this Decree do not modify or absolve them from any prospective obligation to comply with the Act or its implementing regulations or any other federal statute or regulation.

25. Nothing in this Decree shall affect FDA's authority to suspend or revoke any applications pursuant to 21 U.S.C. § 355(e) or either party's ability to take any other action authorized by the Act or its implementing regulations, including any action related to the Juxtapid REMS Program.

FINANCIAL PROVISIONS

26. Should Defendants fail to comply with any provision of this Decree, the Act, or its implementing regulations with respect to the operation of the Juxtapid REMS Program, Aegerion shall pay to the United States of America ten thousand dollars ($10,000) in liquidated damages for each such violation of this Decree, the Act, and/or its implementing regulations, and an additional ten thousand dollars ($10,000) in liquidated damages per day, per violation, for each violation of this Decree, the Act, and/or its implementing regulations with respect to the operation of the Juxtapid REMS Program. The total payments under this Paragraph shall not exceed one million dollars ($1,000,000). Defendants understand and agree that the liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit

the ability of the United States to seek, and the Court to impose, additional civil or criminal penalties based on conduct that may also be the basis for payment of the liquidated damages.

27. Aegerion shall pay all costs of all FDA inspections, investigations, analyses, examinations, sampling, reviews, document preparation, testing, travel, and subsistence expenses that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree, at the standard rates prevailing at the time costs are incurred. For the purposes of this Decree, inspections include, but are not limited to, FDA's review and analysis of Defendants' claims for their products in the product labels, labeling, promotional materials, and any and all websites or any other media owned or controlled by or related to Aegerion or their articles of drug. As of the date that this Decree is signed by the parties, these rates are: $90.65 per hour and fraction thereof per representative for inspection or investigative work; $108.83 per hour or fraction thereof per representative for analytical or review work; $0.54 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses. FDA shall submit a reasonably detailed bill of costs to Aegerion. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

28. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Aegerion shall, in addition to other remedies, reimburse the United States for its attorneys' fees and overhead, investigational and analytical expenses, expert witness

fees, travel expenses incurred by attorneys and witnesses, and court costs relating to such contempt proceedings.

GENERAL PROVISIONS

29. Defendants shall address all communications required under this Decree to Director, Office of Compliance, CDER, Building 51, Room 5270, 10903 New Hampshire Ave., Silver Spring, MD 20993, shall prominently mark the envelope as "DECREE CORRESPONDENCE," and shall reference this civil action by case name and civil action number. Unless otherwise specified, all notifications, certifications, reports, correspondence, and other communications to Defendants required by the terms of this Decree shall be addressed to Aegerion's Chief Legal Officer with copy to Aegerion's President, Aegerion Pharmaceuticals, Inc., One Main Street, Cambridge, MA 02142.

30. If any deadline in this Decree falls on a weekend or federal holiday, the deadline shall be continued to the next business day.

31. The parties may at any time petition each other in writing to modify any deadline provided herein, and if the parties mutually agree in writing to modify a deadline, such extension may be granted without seeking leave of Court.

32. All decisions conferred upon FDA in this Decree or under the Act or its implementing regulations shall be vested in the discretion of FDA. FDA's decisions shall be final and, if challenged, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

33. In all instances where FDA is required to provide written notification to Defendants under this Decree, FDA's silence shall not be construed as a substitute for written notification.

34. If, and for so long as, an individual Defendant ceases to be employed by and to act on behalf of Aegerion or any of its subsidiaries, franchises, affiliates, or "doing business as" entities, then that individual shall not be subject to this Decree, except as to such individual's act(s) or failure(s) to act under this Decree prior to the time such individual ceased to be employed by and to act on behalf of Aegerion or any of its subsidiaries, franchises, affiliates, or "doing business as" entities.

35. If Defendants have maintained a state of continuous compliance with the Juxtapid REMS Program, the Act, its implementing regulations, and this Decree for at least 60 months after entry of this Decree, Defendants may petition the Court for relief from this Decree, and the Government will not oppose the petition.

36. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this _____ Day of _____, 2017

_____
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to entry of the foregoing Decree:

FOR DEFENDANTS	FOR PLAINTIFF
 CHARLES M. GERRITS individually, and on behalf of AEGERION PHARMACEUTICALS, INC.	WILLIAM D. WEINREB Attorney for the United States Acting Under 28 U.S.C. § 515
GREGORY H. LEVINE Ropes & Gray LLP 2099 Pennsylvania Avenue NW Washington, DC 20006-6807 T +1 202 508 4831 F +1 202 383 9822	KRISS BASIL Assistant United States Attorney John Joseph Moakley United States Federal Courthouse 1 Courthouse Way, Suite 9200 Boston, MA 02210 CHAD A. READLER Acting Assistant Attorney General JOSHUA I. WILKENFELD Acting Director, Consumer Protection Branch
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The undersigned hereby consent to entry of the foregoing Decree:

FOR DEFENDANTS	FOR PLAINTIFF
CHARLES M. GERRITS individually, and on behalf of AEGERION PHARMACEUTICALS, INC.	WILLIAM D. WEINREB Attorney for the United States Acting Under 28 U.S.C. § 515
 GREGORY H. LEVINE Ropes & Gray LLP 2099 Pennsylvania Avenue NW Washington, DC 20006-6807 T +1 202 508 4831 F +1 202 383 9822	KRISS BASIL Assistant United States Attorney John Joseph Moakley United States Federal Courthouse 1 Courthouse Way, Suite 9200 Boston, MA 02210 CHAD A. READLER Acting Assistant Attorney General
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FOR DEFENDANTS	FOR PLAINTIFF
_____ individually, and on behalf of AEGERION PHARMACEUTICALS, INC.	WILLIAM D. WEINREB Attorney for the United States Acting Under 28 U.S.C. § 515
GREGORY H. LEVINE Ropes & Gray LLP 2099 Pennsylvania Avenue NW Washington, DC 20006-6807 T +1 202 508 4831 F +1 202 383 9822	KRISS BASIL Assistant United States Attorney John Joseph Moakley United States Federal Courthouse 1 Courthouse Way, Suite 9200 Boston, MA 02210 CHAD A. READLER Acting Assistant Attorney General
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